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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SHAH-2

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EXAMINER

STAPLES, MARK

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/776,711	Applicant(s) SHAH, MRUGESH	
	Examiner Mark Staples	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3, 9, and 11-16 are pending and at issue.

Applicant's arguments filed on 03/07/2008 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections that are Withdrawn

2. The objection to the title is withdrawn in light of Applicant's amendment of the title.
3. The objection to the abstract is withdrawn in light of Applicant's amendment of the abstract.

Claim Rejections Withdrawn - 35 USC § 112, Second Paragraph

Relative Term

4. The rejection of claims 1, 3, 9, and 11-16 in recitation of the relative term "synthetic" under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn. Applicant's arguments filed 03/07/2008 are persuasive.

Rejections that are Maintained

Omitting Essential Elements

Claim Rejections Maintained - 35 USC § 112, Second Paragraph

5. The rejections of claims 1, 3, 9, and 11-15 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements are maintained (for the rejections, see section 8 of the Office action mailed on 01/22/2007). Contrary to Applicant's assertion, it has been established that essential elements are omitted (see section 8 of the Office action mailed on 01/22/2007). Applicant has not provided support for where the omitted elements may be found in the originally filed application. Applicant does not rebut the omission of the essential elements. Thus the rejections are maintained.

Claim Rejections Maintained - 35 USC § 112 First Paragraph

New Matter

6. The rejections of claims 1, 3, 9, and 11-16 for reciting new matter of "synthetic petroleum" and "synthetic coal" under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. It has been established that the terms "synthetic petroleum" and "synthetic coal" are not found in the originally filed application (see section 15 of the Office action mailed on 12/1//2007). Applicant has not provided support for the terms "synthetic petroleum" and "synthetic coal" in the originally filed application. Applicant does not rebut the lack of support for these terms.

Furthermore, the unsupported terms expand the scope of the claims (see section 15 of the Office action mailed on 12/1//2007). Thus the rejections are maintained.

Lack of Enablement

7. The rejection of claims 1, 3, 9, and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

Applicant's arguments filed 03/07/2008 have been fully considered but they are not persuasive.

Applicant initially argues that the problems encountered in "commercially viable biofuel production" have no bearing on enablement of the instant claims. (Biofuel and fuel are interchanged throughout the following discussion.) First, the claims do not exclude "commercially viable biofuel production" which the instant specification attempts to achieve (see p. 6 lines 5-8). Thus such production is relevant to the instant claims. Second, even those references which specifically address commercial biofuel (or fuel) production also address non-commercial biofuel production, usually research biofuel production, in order to understand the fundamentals and overcome the art recognized and severe problems in any biofuel production. Third and importantly, the claims recite methods with limitations of: conversion of substances into fuel (preamble of claim 1), improving methods of conversion of substances into fuel (preamble of claim 9), determining whether productivity improved (step g in claim 9), and commercial production (claim 16). The cited references address the difficulties of these methods, including difficulties that have not, even in the current state of the art, been overcome

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on research or commercial levels. Thus the broad as well as the specific disclosures, whether commercial or non-commercial, of the cited art are relevant to the instant claims (as already given in the preceding Office actions). Applicant's argument that the cited art is not relevant to the instant claims is incorrect.

The nature of the invention and breadth of claims

Applicant has not argued against the breadth of the instant claims.

Thus the breadth of the claims is to any mixture of synthetic components to be found in coal and petroleum or to those that resemble components found in coal and petroleum (see p. 6 and 7 of Office Action mailed on 12/11/2007).

The unpredictability of the art and the state of the prior art

Zaldivar et al.

As already noted above the claims do recite the limitation of "commercial production" and thus prior art which addresses commercial production is relevant to the instant claims. The claims also recite production of fuel (see for example, claim 12) and "Fuel ethanol production" is the subject of the reference by Zaldivar et al. (see Title). And Zaldivar et al. specifically addresses fuel production from microorganisms and conveys this is a general problem, not limited to commercial production ("commercial" does not even appear below):

“The lack of a microorganism able to ferment efficiently all sugars released by hydrolysis from lignocellulosic materials has been one of the main factors preventing utilization of lignocellulose. Thus, an obvious target in the field of metabolic engineering has been the tailoring of such a microorganism, combining advantageous traits from different microorganisms with classical procedures such as random mutagenesis.

This review compares a biomass-derived fuel (ethanol) to a fossil fuel (gasoline), summarizes the current status of bioethanol production, discusses the efforts to construct a suitable microorganism for lignocellulose fermentation, briefly describes a model process emphasizing the importance of process integration, and provides visions for the future prospects for this technology” (bottom of p. 17 to top of page 18).

The lack of a microorganism is a problem for any fuel production by microorganisms, including the claimed invention. Applicant does not contest the teachings of Zaldivar et al., only contending that they are not relevant to the instant claims. However, the instant claims are to the same production as addressed by Zaldivar et al. both generally and specifically, i.e., the “commercial production” of instant claim 16). Thus the uncontested teachings of Zaldivar et al. are relevant to the instant claims.

Zaldivar et al. and Unpredictability of Gene Transfection

Applicant (see pages 14 and 15) is incorrect, relevant teachings of Zaldivar et al. were quoted from the reference for ease of review, there was no “dissecting away”. These relevant teachings stand alone whether quoted or seen in context. Regardless the teachings of “industrial background” and “industrial purposes” of Zaldivar et al. are relevant and especially relevant to the “commercial production” of instant claim 16.

Jeffries et al.

Applicant again argues that commercial applications are not relevant to the instant claims but such are relevant and especially relevant to instant claim 16.

Lin et al.

Examiner does not agree with Applicant's interpretation that Lin et al. enable fuel production from lignocellulose. Lin et al. conclude that "optimism is high" for such production and that Sweden "could" (and not "has") become self sufficient from such production. Applicant again argues that commercial applications are not relevant to the instant claims but such are relevant and especially relevant to instant claim 16.

Unpredictability of Conversion of Solid Fuels and Oil Tars

Examiner does not agree with Applicant's interpretation of Hamme et al. While it is known that n-alkane metabolism and their genes exist, this does not enable using them to produce fuel. Hamme et al. speaks on the processes explicitly: ". . . the specifics of individual systems and the diversity of systems are yet to be fully described . . . " as provided by Applicant. As given in the last Office action, Hamme et al. maintain that hydrocarbon metabolism needs more basic work in enzymology and protein biochemistry in order to be understood. The claimed invention is to an operable system, that is to produce complex fuels, where the art teaches that such systems for n-alkanes, being but one component of a such a complex fuel, are not known fully described and not adequately understood.

Unpredictability of Isolating Genes for Conversion

Even given that regulation and clustering of genes is known, it does not follow that these processes are for isolating genes much less for isolating genes for conversion. Regulation and clustering are effects and conditions of the genes and are not the genes themselves. The instant claims specifically recite isolating the genes for conversion and do not shed light on how known gene regulation and/or clustering would lead to isolation of those genes and production of fuel.

Unpredictability of Producing Synthetic Coals or Synthetic Petroleum Using Transfected Microorganisms

Thus in view of the prior and current art which teach that isolation of a single gene for production of one fuel substance is unpredictable and has not been achieved for many substances and that the instant claims recite isolation of genes (that is more than a single gene) and production of mixtures of fuel substances (that is more than one substance), the claims are not enabled.

Quantity of Experimentation

Applicant again argues that the cited references are directed to commercial/industrial production and thus do not support the extremely large quantity of experimentation needed to arrive at Applicant's claimed invention, even though the

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claims specifically recite production and "commercial production" (see claim 16). This argument has already been address above and in the prior Office actions.

Furthermore, titles of the cited references do not even contain the word "commercial" or reference to such, as seen in the list below.

Hamme et al., Recent Advances in Petroleum Microbiology, *MICROBIOLOGY AND MOLECULAR BIOLOGY REVIEWS*, Dec 2003, p. 503-549 Vol. 67, No. 4.

Zaldivar et al., Fuel ethanol production from lignocellulose: a challenge for metabolic engineering and process integration, *Appl Microbiol Biotechnol* (2001)56:17-34.

Jeffries et al., Metabolic engineering for improved fermentation of pentoses by yeasts, *Appl Microbiol Biotechnol* (2004) 63: 495- 509.

Lin et al., Ethanol fermentation from biomass resources: current state and prospects, *Appl Microbiol Biotechnol* (2006) 69: 627- 642.

Applicant has not argued against the references above disclosing the extremely large quantity of experimentation necessary for conversion of substances into fuels, but incorrectly contends that disclosures of the references are not relevant to the instant claims. The disclosures are relevant. Thus it is maintained that the claimed invention would entail an extremely large quantity of experimentation, as evidenced by the references cited, to arrive at Applicant's claimed invention, if indeed the claimed invention could be made or used.

Working Examples

There is no working example in the instant application.

Applicant contends that the instant application provides a “prophetic working example” which is a contradiction in terms. “A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved” (see the first paragraph of MPEP § 2164.02).

The specification provides a prophetic example, not a working example. Applicant provides no support for a working example in the specification. In ascertaining enablement, working examples or lack thereof are considered (see MPEP § 2164.02 and the section titled NONE OR ONE WORKING EXAMPLE).

Guidance in the Specification

Choi et al.

Even given that Choi et al. produce one fuel component from a microorganism, this does not enable Applicant’s claimed invention of producing the complex mixtures of synthetic coals and petroleums from a microorganism. The teachings of Choi et al. and the elaborate procedures necessary which did not guarantee success are a backdrop to the claims of the instant invention and the instant specification which lacks guidance on how to do that which the art has been unable to do. One of ordinary skill in the art could not make or use the claimed invention as the art provides no guidance on this and the instant specification provides no guidance on this.

Applicant again argues that commercial applications are not relevant to the instant claims but such are relevant and especially relevant to instant claim 16.

a. Lack of Guidance for Gene Transfection

The teachings of Zaldivar et al. as cited in the previous Office Action do not support Applicant contention that transfecting a gene for subsequent expression is routine as a cell/microorganism is complex and the consequences of genetic changes are difficult to predict. Even if transfecting a gene is somewhat routine, transfecting a suite of genes which must subsequently act in proper concert is not and this is the claimed invention, which is to “genes” and not a “gene” for producing mixtures of substances, not just one substance.

b. Lack of Guidance for Gene Identification and Isolation

Claim 1 recites “isolating from the starting microorganisms the genes responsible for the conversion ability”. Applicant contends that the specification provides an “exemplary subtraction hybridization protocol”. Examiner does not find such a “protocol” in the specification. What is given in the specification is a general concept of subtractive hybridization, which at best and which is not guaranteed, yields some nucleic acids which are found in one organism but not another. The general concept by itself does not necessarily identify genes, especially specific genes, and especially those which might be responsible for conversion of substances into fuel. Applicant

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provides no evidence of these things being accomplished or that they could be accomplished.

Furthermore, the claims recite "genes responsible for conversion" (see for example claims 1 and 14). The lack of guidance in the specification would not allow one of ordinary skill in the art to identify "genes for conversion", as how this identification is done is lacking in the specification. There is no guidance to identify these genes, only the contention that they would be somewhere in the vast array of nucleic acids which are different in one organism from another. It is noted also that not one gene but "genes" plural are recited. Thus one ordinary skill in the art is left to attempt further research to find how many are genes are needed and to isolate them all and then to transfect them into another microorganism in an unknown process which would cause them to be expressed in an unknown manner that would convert complex starting materials into complex fuel mixtures.

Additionally, the instant specification admits that to produce the claimed microorganism to produce fuel would only be an "attempt" as follows.

"Following isolation of target sequences using subtractive hybridization, they could also be directly transfected into a host microorganism, using conventional techniques, **to attempt** to produce a microorganism capable of producing petroleum from solid fossil fuels in a highly efficient, commercially viable manner" (emphasis by Examiner, see p. 6 lines 5-8).

The specification does not provide that the microorganism will be achieved. Note also that the specification is clearly directed to producing fuels: ". . . in a highly efficient, **commercially** viable manner" (emphasis by Examiner).

c. Lack of Guidance for Suitable Conversion & Lack of Guidance for Obtaining Synthetic Coals and/or Synthetic Petroleum

Applicant argues that the conditions for suitable conversion are routine and thus need not be incorporated into the specification. Applicant provides no evidence that such conditions are routine. Examiner has reviewed the art and has not found evidence of any such routine conditions for production of mixtures of fuel substances.

Level of Skill in the Art

Applicant concurs that the level of skill in the art is deemed to be high.

Conclusion

Analysis using the Wands factors support the non-enablement of the newly claimed invention. There at least five areas of critical subject matter where the application is not enabled: (1) identifying a target microorganism which is capable of converting complex starting materials into complex fuel mixtures (2) isolating the suite of genes responsible for the fuel conversion ability from the target microorganism, (3) transfecting the suite of genes into a host organism so the genes can be expressed in a manner which causes complex starting materials to be converted into complex fuel mixtures by the now transfected microorganism (4) providing conditions for suitable conversion by the transfected microorganism including those conditions that would cause the suite of genes to be expressed and functional and also would make the starting materials available to the transfected microorganism for conversion, and (5) obtaining the complex fuel mixtures of synthetic coal and or synthetic petroleum from the conversion by the transfected microorganism. As the claims contain this subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, the claims are not enabled.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
/M. S./
Examiner, Art Unit 1637
June 9, 2008

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637